



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

NOV 16 1998 8 32 6 '98 NOV 18 P2:11

Ms. Ann Holden
Standard Process, Inc.
1200 West Royal Lee Drive
Palmyra, Wisconsin 53156

Dear Ms. Holden:

This is in response to your letters of November 15, 1998 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submissions state that Standard Process, Inc. is making the following claims, among others, for the products:

Cyruta[®] and Cyruta-Plus[®]

"...preventing fluid leakage and swelling resulting from burns and radiation"

Betafood[®]

"High homocysteine has also been associated with elevated blood cholesterol"

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate a disease, namely, the consequences of burn and radiation injury and hypercholesterolemia. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

97S-0163

LET-231

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Minneapolis District Office, Office of Compliance, HFR-MW340

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file)

HFS-450 (r/f, file)

HFD-310 (BWilliams)

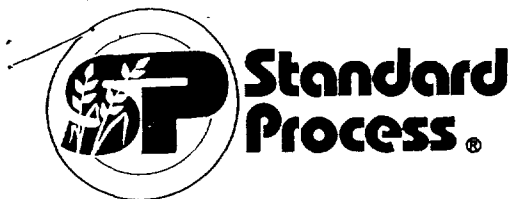
HFD-314 (Aronson)

HFS-600 (Reynolds)

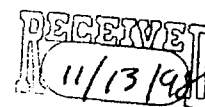
HFS-605 (Bowers)

GCF-1 (Dorsey)

f/t:HFS-456:rjm:11/13/98:docname:62267.adv:disc33



November 15, 1998



The Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. Street S.W.
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Both the tops and the root of the beet contain folic acid, a vitamin essential for maintenance and repair of the gastrointestinal tract. Both beet tops and tubers also have potassium, helping to balance the high sodium intake of most Americans. Adequate potassium is needed for proper muscle functioning and blood pressure control.*
- (2) Beet fiber modulates insulin production.*
- (3) It is known that high homocysteine levels normalize in response to nutrients which aid in the conversion of homocysteine to the amino acid methionine. These include betaine, its precursor choline, the vitamin folic acid, and vitamins B₆ and B₁₂. High homocysteine has also been associated with elevated blood cholesterol.*
- (4) Beets may maintain normal liver function. In the presence of tissue-damaging alcohol, betaine may maintain normal liver metabolism function.*

These statements are made for a dietary supplement containing beet root powder, vacuum dried beet leaf juice, oat flour, honey and vacuum dried beet root juice. The name of the product is Betafood®.

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The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden
Standard Process Inc.





November 15, 1998

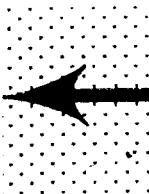
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11/13/98

The Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. Street S.W.
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Buckwheat contains rutin, a phytochemical of the flavonoid group and a powerful anti-oxidant, that protects the body against a variety of damaging oxidative toxins, especially those released by the body from mineral-fiber irritation. By itself, rutin is a more potent free radical quencher than either vitamin C or vitamin E.*
- (2) Anti-oxidants - rutin and quercetin help support the skin. Rutin and quercetin (another anti-oxidant found in buckwheat) strongly protect the skin from oxidative damage, even protecting the nerves within the skin.*
- (3) Soluble fiber and rutin found in buckwheat helps maintain the cardiovascular system. The soluble fiber in buckwheat can help maintain a proper balance between high and low density lipoproteins. Furthermore, rutin prevents the oxidation of low-density lipoprotein in artery walls. As an anti-oxidative, rutin also minimizes oxidative damage in red blood cells, especially to delicate cell walls (and to important fats embedded in those walls), and to essential oxygen-carrying hemoglobin. Rutin maintains the integrity of vein walls, thus preventing fluid leakage and swelling resulting from burns and radiation. It also helps to keep the blood thin, thus encouraging its free flow through the circulatory system, primarily in peripheral arterial systems.*
- (4) Quercetin, found in buckwheat, helps maintain orderly cell growth in breast and other tissues.*



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These statements are made for a dietary supplement containing vacuum dried buckwheat leaf juice and seed, honey, bovine adrenal Cytosol Extract, ascorbic acid, oat flour, and calcium stearate. The name of the product is Cyruta-Plus®.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden
Standard Process Inc.





November 15, 1998

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11/13/98

The Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. Street S.W.
Washington, DC 20204

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- (2) Anti-oxidants - rutin and quercetin help support the skin. Rutin and quercetin (another anti-oxidant found in buckwheat) strongly protect the skin from oxidative damage, even protecting the nerves within the skin.*
- (3) Soluble fiber and rutin found in buckwheat helps maintain the cardiovascular system. The soluble fiber in buckwheat can help maintain a proper balance between high and low density lipoproteins. Furthermore, rutin prevents the oxidation of low-density lipoprotein in artery walls. As an anti-oxidative, rutin also minimizes oxidative damage in red blood cells, especially to delicate cell walls (and to important fats embedded in those walls), and to essential oxygen-carrying hemoglobin. Rutin maintains the integrity of vein walls, thus preventing fluid leakage and swelling resulting from burns and radiation. It also helps to keep the blood thin, thus encouraging its free flow through the circulatory system, primarily in peripheral arterial systems.*
- (4) Quercetin, found in buckwheat, helps maintain orderly cell growth in breast and other tissues.*

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These statements are made for a dietary supplement containing vacuum dried buckwheat leaf juice and seed, inositol, honey, bovine adrenal Cytosol Extract, ascorbic acid, oat flour, and calcium stearate. The name of the product is Cyruta®.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden
Standard Process Inc.

